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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,458	02/11/2000	Michael R. Rosen	61020-A/HOW/PJP	6325

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Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

[REDACTED] EXAMINER

OROPEZZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 02/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/505,458	ROSEN ET AL. <i>cn</i>
	Examiner	Art Unit
	Frances P. Oropeza	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 January 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-60 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-60 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-60 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Specifically, claims 1(2), 5, 10-11, 12 (2), 20(2), 24, 28-31, 39(2), 43, 47-49, 50(2), 58(2), 59(2) and 60(2) contain a phrase or phrases such as: "contacting ... pairs to an/the epicardial surface", "pacemaker to apply ... signals to the epicardial surface", "containing ... pairs to an epicardial vein", "containing ... pairs into an epicardial vein", "placing electrodes into heart ventricles", "having ... pairs ... for contacting an epicardial surface", "delivering ... signals to the epicardial surface", "columns for contacting and epicardial surface", "pacemaker for delivering ... signals to the epicardial surface", "strip containing... pairs to the epicardial surface" and "delivering ... signals to the epicardial surface" which amounts to inferential recitation of the body, which renders these claim non-statutory.

To address the understood intent of the applicant and avoid the 35 U.S.C. 101 rejections, as an example, the phrase "linked multiple electrode pairs adapted to be contacting the epicardial surface" is suggested to replace the phrase "contacting linked multiple electrode pairs to the epicardial surface".

Appropriate correction of all claims is required.

Specification

3. The description portion of this application contains a list of references on pages 46-52.

This list of references must be removed from the specification and included as an appendix. A reference to the newly added appendix should be included at the beginning of the specification.

4. On page 18, line 10, "hearing" should be --heart--.

Claim Objections

5. The disclosure is objected to because of the following informality: In claim 50, line 4, "and a, pacemaker" should be --and a pacemaker--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 5, 9, 10, 21, 24, 34, 40, 43, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 9, 10, 21, 24, 40, 43, 47 and 48 are dependent claims with the phrase "linked multiple electrode pairs". The related independent claim also contains "linked multiple electrode pairs". If the "linked multiple electrode pairs" of the dependent claim are the same as the "linked multiple electrode pairs" of the independent claim, "linked multiple electrode pairs" in the dependent claims should be -- the linked multiple electrode pairs--.

In claim 34, lines 1-2, "the at least two electrode pairs" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in–
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
 - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 9-11, 20, 28-30, 39 and 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Prutchi (US 6152882). Prutchi discloses an apparatus and method for chronic measurement of monophasic action potentials (abstract and c 16, ll 19-44). The embodiment of this invention shown in figure 22B is an implantable pacing device for chronically recording the MAP signals and determining the duration of the refractory periods (c 29, ll 51-56). The device includes an implantable housing (352), a lead or catheter (351) with a plurality of electrodes for sensing, pacing and electroporating (c 29, ll 57-65), an electroporating unit (354), a controller (362) and a pacing core (350). The device can determine and manage the effective refractory period of the cardiac tissue (c 30, l 49 – c 31, l 20). The electroporating unit (354 / 30), containing a pulse generator (32), controllably applies electrical current pulses having a duration, shape, polarity and magnitude sufficient to cause reversible dielectric breakdown of the cell membranes (c 17, l 62 – c 18, l 5). The brief pulses are applied to prevent electrical uncoupling of the cell layers (c 20, ll 34-37). The lead can be a catheter (50) and electrodes (52 and 54)

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(c 19, ll 40-49) and the lead can be placed in the ventricle (c 20, ll 16-23). An epicardial electrode, with holes for sewing the electrode to the heart, can be used with the invention (c 20, ll 55-67). The electrode and lead is made of an electrically insulating biocompatible material (c 20, ll 60-64). The plurality of electrodes on the catheter (figure 13) are arranged in pairs (c 23, ll 3-14). The geometric arrangement of the plurality of electrodes can vary depending on the application (c 23, ll 26-30). Each electrode can be controlled individually using multiplexing and switching circuits to enable multiple pairing and stimulation configurations (c 23, ll 32-38). An electrode array, shown in figure 14, can be used with this invention (c 23, ll 56-61).

This invention relates to treating the heart using electrical excitation of the electrically excitable and electrically coupled cardiac muscle cells (c 1, ll 12-27).

The heart can be treated by specifying electrical stimulation to alter the effective refractory period of the heart (c 2, ll 3-29), hence the device and apparatus disclosed by Prutchi treats the heart to alter the effective refractory period.

Electrical stimulation of the cardiac tissue is believed to change the electrical conductivity properties of the gap-junctions that couple the cardiac muscle cells. Changes in ion components may also play a role in the change in electrical conductively ultimately modifying the current flowing between cells (c 4, l 63 – c 5, l 14). The Applicant's reference, Lodish pp 640 and 641, states opening the Na⁺, K⁺ and Ca 2+ (ion) channels are essential to conduction of an electrical impulse in a nerve cell. The device and apparatus disclosed by Prutchi treats the heart to remodel gap junctions and to induce ion channel remodeling.

Claim Rejections - 35 USC § 103

8. Claims 2, 4, 5, 12, 13, 15, 21, 23, 24, 31, 32, 34, 40, 42, 43, 50, 51, 53 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi (US 6152882) in view of Edwards et al. (US 5681308). As discussed in paragraph 7 of this action, Prutchi discloses the claimed invention except for the 7cm x 1 cm (claims 4, 23 and 42) strip (claims 2, 13, 21, 32, 40 and 51) of electrode material having linked multiple electrode pairs, where the pairs are arranged in two columns (claim 12, 31 and 50) with one electrode in each pair in one column and the other electrode in each pair in the other column (claim 5, 15, 24, 34, 43, 53 and 58-60).

Edwards et al. disclose an analogous mapping apparatus and teach that it is known to use a circuit (38) mounted on a membrane support (16) to serve as a cardiac electrode which provides columns of individually controlled treatment electrodes (34) which can be multiplexed to enable stimulation of electrode pairs (figure 7 and c 7, ll 38-52). Absent any teaching of criticality or unexpected results, it is understood the electrode can be configured as a 7cm x 1 cm strip with only two columns of electrodes. The configuration change is an obvious change in shape based on the specific application. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and method for chronic measurement of monophasic action potentials as taught by Prutchi, with the electrode as taught by Edwards et al. to provide a flat electrode with multiple electrode measurement and stimulation configurations so the cardiac tissue can be more effectively treated.

9. Claims 3, 7-8, 14, 17-19, 22, 26-27, 33, 36-38, 41, 45-46, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi (US 6152882) and Edwards et al. (5681308)

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in view of Dahl et al (US 5203348). As discussed in paragraph 8 of this action, modified Prutchi discloses the claimed invention except for:

- the electrode strip of polyurethane (claims 3, 14, 22, 33, 41, and 52),
- the electrode comprised of platinum or consisting essentially of unalloyed platinum (claims 7-8, 17-18, 26-27, 36-37, 45-46 and 55-56), and
- the electrode connected to an insulated stainless steel wire (claim 19, 39 and 57).

Dahl et al disclose an electrode and teaches that it is known to fabricate an electrode with a platinum or platinum alloy conductor or conductor with a stainless steel core (c 5, ll 19-36), and a lead with a medical grade polyurethane sheath and a stainless steel coated conductor (c 5, ll 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified apparatus and method for chronic measurement of monophasic action potentials as taught by Prutchi, with the materials of construction as taught by Dahl et al.. One have ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

10. Claims 6, 16, 25, 35, 44 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi (US 6152882) and Edwards (US 5681308) in view of Ideker (US 5873896). As discussed in paragraph 8 of this action, modified Prutchi discloses the claimed invention except for the electrode pair being 2mm from each other and the electrode pairs being spaced at lease 5 mm apart. Idecker teaches a cardiac device for reducing arrhythmias and teaches that it is known to use an electrode configuration of an elongate primary strip with a plurality of electrodes positioned at spaced intervals, e.g. 1-4 millimeters (c 3, ll 2-4). Therefore it would have been

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obvious to one having ordinary skill in the art at the time the invention was made to modify the modified apparatus and method for chronic measurement of monophasic action potentials as taught by Prutchi, with the electrode spacing as taught by Ideker to provide electrode spacing known to effectively reduce cardiac arrhythmias.

Conclusion

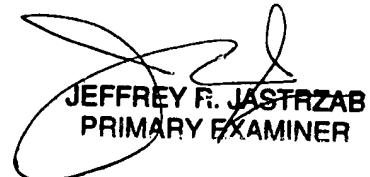
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

JPO
2/18/02



JEFFREY R. JASTRZAB
PRIMARY EXAMINER